

## Purpose of this Annex

This Annex sets out publicly available documentary records relating to selected UK legislative models that address the interaction between lawful medical use of controlled substances and criminal law.

The material is presented for comparative reference purposes only.

Inclusion of a document does not imply that it formed part of the decision-making process for the rescheduling of cannabis-based products for medicinal use (CBPMs).

The Annex adopts the same evidential structure and discipline as Annex A to support consistent cross-reference, scrutiny, and verification.

Section 1 – Road Traffic Act 1988: Section 5A (Drug-Driving Regime)						
Ref	Date	Document title (exact / published)	Issuing body → Recipient	Purpose / scope (as evidenced by content)	Key points relevant to regulatory architecture	Public link
B1.1	30-May-12	Impact Assessment: Drug Driving Offence (Crime and Courts Bill, Clause 27)	Department for Transport / Home Office → Parliament	Impact assessment accompanying primary legislation proposing a new drug-driving offence	Considers criminal-law impact of drug-driving offence; includes statutory medical defence; explicitly considers equality and disability impacts arising from lawful prescribed drug use	<a href="https://assets.publishing.service.gov.uk/media/5a79578bed915d07d35b4aab/ja-drug-driving-offence.pdf">https://assets.publishing.service.gov.uk/media/5a79578bed915d07d35b4aab/ja-drug-driving-offence.pdf</a>
B1.2	25-Apr-13	Crime and Courts Act 2013 (section 56)	UK Parliament	Primary legislation amending the Road Traffic Act 1988	Inserts section 5A into the Road Traffic Act 1988; creates strict-liability offence with statutory medical defence for prescribed drugs taken in accordance with medical advice	<a href="https://www.legislation.gov.uk/ukpga/2013/22/section/56/enacted">https://www.legislation.gov.uk/ukpga/2013/22/section/56/enacted</a>
B1.3	07-Mar-14	The Drug Driving (Specified Limits) (England and Wales) Regulations 2014	UK Government	Secondary legislation implementing section 5A	Specifies controlled drugs (including THC) and blood concentration limits; completes operational framework for offence and defence	<a href="https://www.legislation.gov.uk/uksi/2014/2868/contents">https://www.legislation.gov.uk/uksi/2014/2868/contents</a>
B1.4	24-Jul-14	Drug Driving (Specified Limits) Regulations – House of Lords debate	UK Parliament	Parliamentary debate	Parliamentary scrutiny of draft specified-limits regulations; records ministerial explanation of safeguards and medical defence	<a href="https://hansard.parliament.uk/Lords/2014-07-24/debates/14072442000159/DrugDriving(SpecifiedLimits)(EnglandAndWales)Regulations2014">https://hansard.parliament.uk/Lords/2014-07-24/debates/14072442000159/DrugDriving(SpecifiedLimits)(EnglandAndWales)Regulations2014</a>
B1.5	02-Mar-15	Commencement of section 5A drug-driving regime	UK Government	Operative commencement milestone	Section 5A offence and specified-limits regime come into force; statutory medical defence becomes operational	<a href="https://www.gov.uk/government/publications/drug-driving-and-medicine-advice-for-healthcare-professionals">https://www.gov.uk/government/publications/drug-driving-and-medicine-advice-for-healthcare-professionals</a>
Section 2 – Pregabalin and Gabapentin Rescheduling (2018–2019)						
B2.1	2016–2017	ACMD advice on pregabalin and gabapentin	ACMD → Home Office	Scientific advisory advice	Recommends control of pregabalin and gabapentin due to misuse and harm; advises classification and scheduling changes	<a href="https://assets.publishing.service.gov.uk/media/5a80e1fded915d74e6230fd2/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf">https://assets.publishing.service.gov.uk/media/5a80e1fded915d74e6230fd2/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf</a>
B2.2	15-Oct-18	Pregabalin and gabapentin to be controlled as Class C drugs	Home Office → Public	Government announcement	Announces intention to amend the Misuse of Drugs Act 1971 and associated regulations following ACMD advice and consultation	<a href="https://www.gov.uk/government/news/pregabalin-and-gabapentin-to-be-controlled-as-class-c-drugs">https://www.gov.uk/government/news/pregabalin-and-gabapentin-to-be-controlled-as-class-c-drugs</a>
B2.3	11-Dec-18	Misuse of Drugs Act 1971 (Amendment) Order 2018 (SI 2018/1356)	UK Government → Parliament	Statutory Instrument (affirmative procedure)	Amends the Misuse of Drugs Act 1971 to classify pregabalin and gabapentin as Class C drugs, extending criminal offences for unauthorised possession and supply	<a href="https://www.legislation.gov.uk/uksi/2018/1356/contents">https://www.legislation.gov.uk/uksi/2018/1356/contents</a>
B2.4	11-Dec-18	Explanatory Memorandum to SI 2018/1356	Home Office → Parliament	Explanatory Memorandum	Explains legal basis, consultation background, and anticipated impacts of Act amendment; summarises impact considerations	<a href="https://www.legislation.gov.uk/uksi/2018/1356/pdfs/uksiem_20181356_en.pdf">https://www.legislation.gov.uk/uksi/2018/1356/pdfs/uksiem_20181356_en.pdf</a>
B2.5	11-Dec-18	Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) (England and Wales and Scotland) Regulations 2018 (SI 2018/1383)	UK Government → Parliament	Statutory Instrument	Amends MDR 2001 and Safe Custody Regulations to place pregabalin and gabapentin in Schedule 3, establishing controlled-drug obligations	<a href="https://www.legislation.gov.uk/uksi/2018/1383/contents">https://www.legislation.gov.uk/uksi/2018/1383/contents</a>
B2.6	11-Dec-18	Explanatory Memorandum to SI 2018/1383	Home Office → Parliament	Explanatory Memorandum	Sets out regulatory consequences of Schedule 3 placement and implementation approach	<a href="https://www.legislation.gov.uk/uksi/2018/1383/pdfs/uksiem_20181383_en.pdf">https://www.legislation.gov.uk/uksi/2018/1383/pdfs/uksiem_20181383_en.pdf</a>
B2.7	21-Nov-18	Misuse of Drugs Act 1971 (Amendment) Order 2018 – House of Lords debate	UK Parliament	Parliamentary debate	Lords debate on affirmative Order; records ministerial explanation of criminalisation and safeguards	<a href="https://hansard.parliament.uk/Lords/2018-11-21/debates/BBF6FE68-F1D9-4CF5-B923-0DD2C1FBE97F/MisuseOfDrugsAct1971(Amendment)Order2018">https://hansard.parliament.uk/Lords/2018-11-21/debates/BBF6FE68-F1D9-4CF5-B923-0DD2C1FBE97F/MisuseOfDrugsAct1971(Amendment)Order2018</a>
B2.8	29-Mar-19	Home Office Circular 019/2018 – Control of pregabalin and gabapentin	Home Office → Police, CJS, health stakeholders	Operational circular / guidance	Provides implementation guidance ahead of commencement; explains enforcement expectations and transition arrangements	<a href="https://www.gov.uk/government/publications/circular-0192018-control-of-pregabalin-and-gabapentin-under-the-misuse-of-drugs-act-1971">https://www.gov.uk/government/publications/circular-0192018-control-of-pregabalin-and-gabapentin-under-the-misuse-of-drugs-act-1971</a>

## Status and Use

This Annex is **descriptive and referential**.

It evidences **legislative models and safeguards that existed in UK law**.

It does **not** assert that these models were considered, rejected, or applied in the CBPM context.

It is intended to support **comparative analysis elsewhere** (including Annex C and FOI-1D).